UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re EDAP TMS S.A. Securities Litigation	No. 1:14-cv-06069-LGS
THIS DOCUMENT RELATES TO: ALL ACTIONS	CLASS ACTION

REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AMENDED COMPLAINT

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Plaintiff's Memorandum in Opposition to Defendants' Motion to Dismiss ("Opp'n") only confirms that the Complaint fails to state a claim for securities fraud. Plaintiff misleadingly suggests that the FDA's May 2013 deficiency letter "derailed" and "doomed" EDAP's PMA application, but this hyperbole finds no basis in particularized factual allegations. Instead, plaintiff's conclusion is based on conflating the few allegations in the Complaint about the contents of the Spring 2013 letter with the FDA's criticism of EDAP's PMA application contained in the July 2014 Briefing Document, which amounts to nothing more than fraud by hindsight. Plaintiff also argues that EDAP failed to respond to the FDA's concern that it had used an "unvalidated" endpoint, but this is simply wrong—in response to the FDA's concern about using an "unvalidated" endpoint, EDAP submitted a supplement to its application using a *new* endpoint that had previously provided the basis for FDA approval of other technologies.

Plaintiff's essential theory—that EDAP's PMA application was a sham and that EDAP knew it—grossly distorts the record and is belied by statements of the very advisory panel members who voted to recommend against approving it. One member stated that EDAP's analysis was done "very rigorously, and very honestly." Dulberg Reply Decl. Ex. O at 171. Another said, "I agree, they have done as good a job as they can do with the data that's out there." *Id.* at 170. A third stated, "I am full of admiration for what [EDAP] did." *Id.* at 242. As set out below, and in the opening brief, the Complaint does not adequately plead a claim for securities fraud, and the Opposition fails rehabilitate plaintiff's deficient allegations of scienter, let alone supply facts sufficient to support the extraterritorial application of Section 10(b).

I. The Complaint Fails To Allege A False Or Misleading Statement

A. The Challenged Statements Are Mostly Inactionable Accurate Statements Of Historical Fact

In moving to dismiss, defendants showed that many of the challenged statements are

accurate statements of historical fact that cannot be misleading as a matter of law. See Defs.' Mem. at 11-12 (citing paragraphs 73, 76, 77, 81, 84, 91, 95, and 97). Plaintiff offers no response, and has therefore conceded that he may not challenge these statements.[1]

B. The Deficiency Letter Does Not Render EDAP's Remaining Statements False Or Misleading

The remaining statements that are not purely historical fact are also inactionable. Plaintiff's Opposition only serves to highlight the fact that the Complaint pleads nothing more than fraud by hindsight. In an effort to convince the Court otherwise, plaintiff (1) *overstates* the alleged contents of the deficiency letter, (2) *conflates* its supposed contents with statements contained in an FDA Briefing Document published at the end of the class period, and (3) *mischaracterizes* EDAP's response to the deficiency letter.[2]

1. The Opposition Overstates The Contents Of The Deficiency Letter

Plaintiff suggests that EDAP's statements in and after May 2014 were misleading because they failed to reveal that the PMA application "had been substantially derailed due to the serious inadequacies identified by the FDA in its Major Deficiency Letter," Opp'n at 13, 23; that "the FDA communicated to EDAP that its application lacked sufficient evidence to support efficacy," Opp'n at 17; that defendants were aware of "fatal defects in their PMA," Opp'n at 26; and that "the FDA informed Defendants that the data supporting its PMA was utterly deficient to support the Company's claims that Ablatherm was effective." Opp'n at 30. These draconian characterizations of the deficiency letter find no support in plaintiff's only source for the actual

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[1] *See, e.g.*, *Guzman v. Macy's Retail Holdings, Inc.*, No. 09-cv-4472, 2010 WL 1222044, at *8 (S.D.N.Y. Mar. 29, 2010) ("Plaintiff does not address this argument in her opposition brief, and therefore has waived this claim."); *Lipton v. Cnty. of Orange, N.Y.*, 315 F. Supp. 2d 434, 446 (S.D.N.Y. 2004) ("This Court may, and generally will, deem a claim abandoned when a plaintiff fails to respond to a defendant's arguments that the claim should be dismissed.").

[2] Plaintiff's argument that EDAP is seeking dismissal on the basis that the deficiency letter is per se immaterial, Opp'n at 15, is a straw man—EDAP never made a materiality argument. Instead, defendants are entitled to dismissal because nothing about the contents of the deficiency letter renders any statement that they made false or misleading.

content of the letter—the transcript of the advisory panel meeting.[3] That transcript establishes only that the letter told EDAP that (1) "the application lacked sufficient evidence to assess effectiveness based in part on the use of an unvalidated endpoint," and (2) the FDA had "concerns about the comparability of the safety profiles of HIFU and alternative treatments." Ex. J at 75; Compl. ¶ 36; Opp'n at 14 (quoting transcript from advisory panel meeting).[4]

Neither of these statements remotely suggests that the PMA application was "derailed" upon EDAP's receipt of the letter. To the contrary, the very purpose of a "major deficiency letter" is to request additional information from a sponsor that the FDA needs in order to complete its review, which the sponsor may discuss with the FDA at a 100-day meeting.[5] *See, e.g., Sarafin v. BioMimetic Therapeutics, Inc.*, No. 3:11-cv-653, 2013 WL 139521, at *18 (M.D. Tenn. Jan. 10, 2013) ("What is clear, however, is that a deficiency letter is not a final FDA decision, but a request for more information, and, in fact, 'very few' PMA are approved without the issuance of a deficiency letter."), *aff'd sub nom. Kuyat v. BioMimetic Therapeutics, Inc.*, 747 F.3d 435 (6th Cir. 2014). If the PMA application indeed was "doomed," the FDA had other tools to convey that message, namely a not-approvable letter or a denial letter.[6]

Plaintiff brushes aside these authorities by asserting that even if a major deficiency letter does not generally portend failure for a PMA application, *this* one somehow did. Not so. The

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[3] Plaintiff concedes that "the Panel meeting" provides his only basis to characterize the deficiency letter. Opp'n at 14.

[4] The FDA explained that the deficiency letter "*raised questions* with respect to the clinical significance of the effectiveness endpoints and analyses and also the comparability of the safety profiles of [Ablatherm and cryotherapy]." Ex. J at 75 (emphasis added).

[5] *See, e.g.*, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm047991.htm ("During the review process, FDA will notify the PMA applicant via major/minor deficiency letters of any information needed by FDA to complete the review of the application.").

[6] *See* Defs.' Mem. at 5-6 (distinguishing "deficiency" letter from "not approvable" letter and "denial" letter). The statistics published on the FDA's website reveal that the overwhelming majority of PMA submissions are met with major deficiency letters, and that they are nonetheless *approved*. The Complaint alleges no facts from which this Court could infer that the deficiency letter that the FDA sent EDAP presented a hurdle any greater than those posed by the deficiency letters issued to other applicants. *See, e.g., Kuyat v. BioMimetic Therapeutics, Inc.*, 747 F.3d 435, 439-40 (6th Cir. 2014) (deficiency letter "questioned BioMimetic's use of an mITT population for the primary effectiveness analysis," but advisory panel later voted to recommend that FDA approve device).

fact that the FDA considered the endpoint that, to that point, EDAP had used for its efficacy analysis to be "unvalidated" was hardly "fatal"; to the contrary, as discussed below, EDAP responded to the deficiency letter by submitting a supplement to the PMA application using a completely different endpoint. Ex. J at 75. Similarly, the fact that the FDA had "concerns" about "the comparability" of safety data did not indicate that the FDA would deny EDAP's PMA; it signified only that the FDA had identified an issue for further discussion and evaluation. *See, e.g.*, *BioMimetic*, 2013 WL 139521, at *4 (no liability even though FDA "expressed concerns" in deficiency letter); *In re Sanofi Sec. Litig.*, No. 13-cv-8806-PAE, 2015 WL 365702, at *23-30 (S.D.N.Y. Jan. 28, 2015) (no liability for failure to disclose FDA "concerns").[7]

2. The Opposition Conflates The Contents Of The FDA's Briefing Document With The Contents Of The Deficiency Letter

Plaintiff claims that EDAP's "statements regarding low morbidity and safety" were incomplete and misleading because they omitted "the fact that the FDA found such a high incidence of adverse events generated by Ablatherm," Opp'n at 16, "the fact that Ablatherm caused significant morbidity," Opp'n at 17 n.8, and that "Defendants were aware that Ablatherm generated a significant number of adverse events and demonstrated 'significant morbidity.'" Opp'n at 21. But these assertions are not based on anything in the record about the content of the deficiency letter.[8] *See* Compl. ¶ 36. Rather, these allegations are all drawn from the FDA's Briefing Document: "The Briefing Document . . . documented high rates of adverse events," Compl. ¶ 105; "The Briefing Document revealed that 'a safety analysis of Ablatherm HIFU . . .

[7] At the very least, it was premature to draw any conclusions about whether the application was "doomed" before the parties' discussion of the deficiency letter at the 100-day meeting. *See, e.g.*, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm047991.htm. Plaintiff makes no allegations about what transpired at that meeting, so there is simply no basis to infer that the application had been "derailed" either before or at that meeting. Indeed, following the 100-day meeting, EDAP supplemented its application, the process continued, and the FDA convened an advisory panel.

[8] *See, e.g., Johnson v. Pozen Inc.*, No. 07-cv-599, 2009 WL 426235, at *20 (M.D.N.C. Feb. 19, 2009) ("Plaintiffs assert that the FDA expressed grave concerns over the long-term safety of Trexima . . . but the record reveals no such statements by the FDA.").

demonstrate *significant morbidity* of the HIFU procedure.'" Compl. ¶ 71. This is classic fraud by hindsight: EDAP's *pre-July 2014* statements cannot become "incomplete and misleading" by their failure to disclose FDA views that only became apparent when the FDA released the "Briefing Document" on July 28, 2014.[9] Accordingly, this Court should dismiss plaintiff's challenges to statements that are only alleged to be "misleading" based on the FDA's July 2014 analysis. Compl. ¶¶ 75, 80, 82, 90, 94, 102.

Not only is it clear that plaintiff has no contemporaneous facts that establish the falsity of EDAP's statements about safety, but it is equally clear that the record *supports* EDAP's statements. *See In re Sanofi*, 2015 WL 365702, at *12 (statements of opinion not false where genuinely believed). For example, one study published in the British Journal of Urology, International analyzing fourteen years of patient data expressly concluded that the study "*demonstrates the efficacy and safety of HIFU* for localized [prostate cancer]." Ex. L (emphasis added). Another study published that the European Association of Urology published, based on an analysis of over one thousand patients treated with HIFU, concluded that HIFU caused "acceptable morbidity." Ex. M.

Contrary to plaintiff's say-so that he is complaining about more than a difference in scientific opinion, Opp'n at 30, the transcript of the advisory panel confirms that the members themselves were divided on the question of whether there "is a reasonable assurance that the Ablatherm . . . is safe for the proposed indications for use (e.g., the device will not expose patients to an unreasonable or insignificant risk of illness or injury)." Ex. O at 233.[10] Three

[9] Even if credited, these allegations do not show any misstatement of fact, but only that EDAP and the FDA held different opinions about Ablatherm's morbidity profile. Defendants' statements that treatment with Ablatherm is associated with a "low" occurrence of side effects and has a "low" morbidity profile are self-evident statements of opinion as to which plaintiff has failed to plead any lack of belief in them, particularly given that (i) in the context of a condition where all treatments cause similar side effects, "low" is inherently a relative term, and (ii) multiple advisory committee panel members voted that Ablatherm is safe. Ex. O at 233.

[10] Defendants previously filed excerpts of the transcript of the July 30, 2014 FDA advisory committee meeting as Exhibit J to the declaration in support of their opening memorandum. Exhibit O contains additional

panelists voted "yes," five voted "no," and one abstained. *Id.* As for side effects, one of the FDA presenters observed that the "high rates of erectile dysfunction" associated with treatment with Ablatherm "are not dissimilar to that reported following surgery or radiation." Ex. O at 88. At the end of the day, plaintiff at most has established an inactionable scientific disagreement.

3. The Opposition Mischaracterizes EDAP's Response To The Deficiency Letter

Adding a new theory not found in the Complaint, plaintiff repeatedly claims that the falsity of EDAP's statements is proven by the "fact" that EDAP "inexplicably ignored the FDA's express warning and continued to use an unapproved endpoint" in response to the deficiency letter, Opp'n at 6, thus guaranteeing the denial of the Company's PMA submission. *Id.* at 14-16. Despite the assistance of an FDA "expert," Compl. at 10, plaintiff has the facts wrong. As the transcript of the advisory panel meeting makes clear, EDAP's initial PMA submission used a performance-based endpoint, the "the Phoenix biochemical success rate at two years." Ex. O at 91. *That* is the "unvalidated" endpoint to which the deficiency letter refers. After receiving the letter, EDAP filed a supplement to its PMA using data based on a *different* endpoint, metastasis-free survival after eight years. *See* Ex. J at 75, Ex. O at 82, 93-94, 154; Pls.' Ex. B at 78. Although the analysis using *that* endpoint did not result in FDA approval in 2014, *that* endpoint was clearly not "unvalidated" or "doomed" to fail. To the contrary, one of the FDA's presenters at the panel hearing stated that "metastasis-free survival is a potentially acceptable endpoint for regulatory action and has been used by the FDA as a basis for approval of other treatments for other malignancies." Ex. O at 81.

Thus, far from *ignoring* the questions raised in the deficiency letter, EDAP appropriately *responded* to them by submitting additional data analysis using a different endpoint. In sum, the

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excerpts from this same transcript. To the extent it would be helpful to review additional context surrounding these excerpts, Defendants will provide the complete transcript at the request of the Court.

plaintiff is wrong about what the deficiency letter *meant*, wrong about what the deficiency letter *said*, and wrong about EDAP's response.[11]

4. Mr. Oczachowski Did Not Misrepresent The Nature Of The FDA's Questions

Nor does the deficiency letter contradict Mr. Oczachowski's statements about the nature of the FDA's questions during the review process. In a November 21, 2013 earnings conference call, an analyst asked whether the FDA's questions "have to do with efficacy of Ablatherm or the HIFU product." Dulberg Decl. Ex. H at 5. In response, Mr. Oczachowski answered, "No, I would say it is more clarification questions . . . it is more on methods and it is more – it is quite variable and it is quite mixed as well." Although plaintiff ignores it, Mr. Oczachowski elaborated on this answer moments later, and stated, "I may have missed explain [sic] that earlier but we are in the next stage of real – that's the real round of questions and answers and again the questions . . . I've got is not kind of challenging the clinical results, but we are to do more on the structure of the trial and again the way to interpret and evaluate the data that are getting out of the trial." Ex. H at 7.

These statements could not have been misleading. The Complaint itself alleges that the deficiency letter stated that EDAP's application "lacked sufficient evidence *to assess effectiveness*" Compl. ¶ 36, rather than challenging the efficacy of the device. The advisory panel transcript says the same thing. Pls.' Ex. B at 78. And plaintiff points to nothing else suggesting that the FDA had questioned the efficacy of the device, as opposed to whether it had sufficient data to make a determination. Plaintiff's attempt to dismiss defendants' argument as "wordplay" ignores the fact that in a fraud case, the actual words matter. There is a significant

[11] Even if it were true that EDAP placed its PMA "at grave risk" by continuing "to use the wrong primary endpoint," Opp'n at 14, which lacks any support and which EDAP firmly denies, that reduces to an allegation of corporate mismanagement that is insufficient to state a claim for securities fraud. *See, e.g.*, *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 562 (S.D.N.Y. 2014).

and obvious difference between questioning whether the device was effective (which did not happen) and questioning whether there was sufficient evidence to *assess* efficacy.[12] At a minimum, Mr. Oczachowski's precision is wholly inconsistent with any intent to deceive. *See infra* at 11-15.

5. Plaintiff's Cases Are Inapposite

The facts of this case bear no resemblance to the egregious omission in *Delcath*—there, defendants disclosed a 7% fatality rate in the treatment arm of their clinical studies but deceptively concealed that there were no fatalities among patients in the control group. *In re Delcath Sys., Inc. Sec. Litig.*, 36 F. Supp. 3d 320, 326, 332 (S.D.N.Y. 2014) (device was associated with "substantial and severe toxicity"). Similarly, in *Transkaryotic Therapies*, plaintiffs alleged that defendants misled the market by describing FDA approval as a "when, not if proposition" despite knowing that the FDA had told the sponsor in a complete review letter that it would *require* the company to conduct additional studies to establish efficacy, and *denied* approval of the company's application based on its existing studies. *In re Transkaryotic Therapies, Inc. Sec. Litig.*, 319 F. Supp. 2d 152, 156, 160-61 (D. Mass. 2004). EDAP *never* expressed even optimism (much less assured investors) that the FDA would approve Ablatherm, and, as explained above, plaintiff does not adequately allege that the deficiency letter conveyed to EDAP any facts contrary to the Company's representations.

Plaintiff's other cases stand for the unremarkable proposition that a company may be liable for securities fraud where it fails to disclose information that directly contradicts its affirmative public statements. For example, in *Amylin*, the court declined to dismiss the complaint where defendants "represented that, in their opinion, the trial results *met the*

[12] The transcript is equally unhelpful to plaintiff. As a member of the FDA advisory panel explained, "It's not that I don't believe the therapy works or doesn't work. It very well may work; I just don't know because the data that's being used is indeterminate …." Ex. O at 183-84.

requirements for FDA approval," while knowing that the FDA expressed "serious doubt on the sufficiency of the trials." *In re Amylin Pharm., Inc. Sec. Litig.*, No. 01-cv-1455, 2003 WL 21500525, at *8 (S.D. Cal. May 1, 2003). Similarly, in *Hemispherx*, the court denied a motion to dismiss where the company announced that the FDA had permitted it to resubmit a new drug application using a reanalysis of previously submitted data, but failed to disclose "the FDA's immediately preceding statement that it would be 'unusual' for such reanalysis to provide sufficient evidence for approval." *Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 346 (E.D. Pa. 2014).[13] These cases have no application here, where there are no well-pleaded factual allegations that EDAP made any representations that were contradicted by any *contemporaneous* communications from the FDA.

C. The Remaining Challenged Statements Are Inactionable Puffery

Defendants also showed that several of the challenged statements were inactionable puffery. Defs.' Mem. at 13-15. In response, plaintiff continues to insist that EDAP's *backward*-looking statements that it *had achieved* "significant" and "major" milestones were somehow "optimistic" statements predicting FDA approval. Opp'n at 20-21. This reading strains credulity, particularly given that EDAP conspicuously refrained from ever promising or predicting FDA approval. No investor could reasonably have interpreted the statements to be anything other than soft and non-predictive. Nor does plaintiff gain ground by insisting that defendants did not genuinely or reasonably believe their statements. Opp'n at 21. *Xoma Corp.* is wholly inapposite—there, unlike here, defendants made statements indicating that FDA approval of a drug was imminent while in the possession of specific facts to the contrary. Opp'n at 21-22 (citing *Warshaw v. Xoma Corp.*, 74 F.3d 955 (9th Cir. 1996)).

[13] The *Viropharma* case is of similar effect—there, the court observed that the defendant's "public statements directly contradict information Viropharma had privately received from the FDA . . . ." *In re Viropharma Inc. Sec. Litig.*, 21 F. Supp. 3d 458, 471 (E.D. Pa. 2014).

Plaintiff also misses the mark with his arguments regarding EDAP's statement that the FDA process was "on track . . . ." Compl. ¶ 80. For one thing, courts across the country have rejected the very argument that plaintiff now tries to raise here—that the phrase "on track" is a statement of present fact and not subject to the safe harbor. *See, e.g.*, *Institutional Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 255-59 (3d Cir. 2009); *Gissin v. Endres*, 739 F. Supp. 2d 488, 507 n.108 (S.D.N.Y. 2010) (citing *Avaya* with approval); *Mogensen v. Body Cent. Corp.*, 15 F. Supp. 3d 1191, 1216-17 (M.D. Fla. 2014); *W. Wash. Laborers-Employers Pension Trust v. Panera Bread Co.*, 697 F. Supp. 2d 1081, 1095 (E.D. Mo. 2010).[14] The statement is also inactionable puffery and cannot support a securities fraud claim. *See, e.g.*, *In re Royal Appliance Sec. Litig.*, 64 F.3d 663, 1995 WL 490131, at *3 (6th Cir. Aug. 15, 1995) (per curiam) (affirming dismissal of statement that defendant was "on track to have a terrific year" as puffery); *Callan v. Motricity Inc.*, No. 11-cv-1340, 2013 WL 195194, at *23 (W.D. Wash. Jan. 17, 2013) ("several courts have concluded that statements that a company is 'on track' are too vague to be actionable").[15]

Equally important, plaintiff fails to allege facts that establish that the May 16, 2013 statement was *false*. The Complaint offers nothing beyond speculation to claim that EDAP had even received the deficiency letter before issuing that press release. *See* Defs.' Mem. at 12 n.16. Moreover, as discussed above, plaintiff fails to plead particularized facts to support his argument that the deficiency letter "derailed" (i.e., knocked "off track") EDAP's PMA submission.

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[14] Contrary to plaintiff's suggestion, Opp'n at 23, the *Dura* court did *not* consider whether a statement using the phrase "on track" constituted a forward-looking statement subject to the PSLRA's safe harbor. *In re Dura Pharms., Inc. Sec. Litig.*, 548 F. Supp. 2d 1126 (S.D. Cal. 2008). The *Dura* court declined to deem as puffery a statement that the defendant was "on track" to bring an inhaler to the market in late 1998 or early 1999, but that was far more predictive of a specific result than EDAP's statement, which in context, referred to the procedural status of the PMA application and not to the likelihood of approval. *Id.* at 1143 n.15. As for plaintiff's claim that EDAP's warnings were "boilerplate," Opp'n at 24, it is hard to imagine how EDAP could have been more specific. *See* Defs.' Mem. at 13. EDAP warned of the precise risks that came to pass.

[15] *See also Rochester Laborers Pension Fund v. Monsanto Co.*, 883 F. Supp. 2d 835, 853 & 868 n.34 (E.D. Mo. 2012) (statements that defendant was "on track" held forward-looking under safe harbor, and "[p]redictions of a company being 'on track' … are also inactionable puffery."); *In re Copper Mountain Sec. Litig.*, 311 F. Supp. 2d 857, 880 (N.D. Cal. 2004) (statements that company was on track to reach revenue earnings expectations "best characterized as inactionable puffery"); *Bavaria Int'l Aircraft Leasing GmbH v. Clayton, Dubilier & Rice, Inc.*, No. 03-cv-0377, 2003 WL 21767739, at *5 (S.D.N.Y. July 30, 2003) (citing with approval First Circuit decision affirming dismissal of challenge to statement that company was "basically on track" as immaterial puffery).

II. The Complaint Fails To Plead Scienter

A. The Complaint Does Not Establish Reckless Conduct

For the same reasons that the Complaint fails to plead *falsity*, it equally fails to plead *scienter*. *See, e.g.*, *In re Sanofi*, 2015 WL 365702, at *19.[16] Thus, the argument that EDAP "touted Ablatherm's supposed safety and low morbidity" despite knowing "of the fatal defects in their PMA" (Opp'n at 26) fails for lack of a predicate—the Complaint does not adequately allege any such "fatal defects." In any event, the record offers strong support for EDAP's views as to the safety and efficacy of treatment with Ablatherm. *See* Defs.' Mem. at 18-19 & n.23.

As to safety, Plaintiff contends that EDAP knew—but failed to disclose—"that use of the product generated numerous serious adverse events." Opp'n at 26. Again, there is no predicate for this hyperbole: neither the FDA, nor anyone else, has *ever* linked treatment with Ablatherm to "serious adverse events." That phrase cannot be found *once* in the advisory panel transcript.[17] To the extent the plaintiff means to say that EDAP failed to disclose *side effects* of treatment with Ablatherm, such as erectile dysfunction, this is demonstrably false—Ablatherm has been used to treat tens of thousands of patients, and the empirical data associated with its use, including adverse events, have been published and are publicly available.[18] *See, e.g.*, *In re Bank of Am. AIG Disclosure Sec. Litig.*, 980 F. Supp. 2d 564, 586 (S.D.N.Y. 2013) ("disclosure of relevant information" negated inference of scienter), *aff'd*, 566 F. App'x 93 (2d Cir. 2014); *In re GeoPharma, Inc. Sec. Litig.*, 399 F. Supp. 2d 432, 452 (S.D.N.Y. 2005) ("Plaintiffs have cited no case, and I am aware of none, where a plaintiff adequately pled scienter based solely on the contradiction between *public* information and the company's public

[16] Plaintiff appears to proceed on a theory of recklessness rather than conscious misbehavior despite liberal references to what EDAP supposedly "knew." Opp'n at 25.

[17] In fact, "[t]he rate of serious side effects, such as recto-urethral fistulae is low." Ex. L at 7.

[18] Plaintiff quotes Mr. Oczachowski in an effort to suggest that the approval of Ablatherm in Europe does not provide a basis to describe treatment with Ablatherm as safe and effective. Opp'n at 28-29. But EDAP's belief was supported not only by the fact of European approvals, but also by the safe and effective *use* of Ablatherm to treat *tens of thousands of patients* in Europe and around the world over nearly two decades. *See, e.g.*, Ex. L.

statements."). The fact that several members of the FDA advisory panel voted "yes" when asked whether Ablatherm "is safe," Ex. O at 233, vitiates any suggestion that EDAP *knew* Ablatherm was *not* safe. *In re Columbia Labs., Inc., Sec. Litig.*, No. 13-cv-4777, 2015 WL 1046166, at *3 (3d Cir. Mar. 10, 2015) (affirming dismissal based, in part, on competing innocent inference provided by multiple panel members voting to approve drug).

Plaintiff's reliance on *Delcath* is misplaced. The Opposition claims "the negativity of the FDA's statements regarding the trial results (including the overwhelmingly negative Panel vote) supports the inference that Defendants acted recklessly in their positive statements to investors." Opp'n at 28 (citing *Delcath*). But the mere fact of an advisory panel vote against approval does not inherently give rise to an inference of scienter. *See, e.g., In re Columbia Labs., Inc. Sec. Litig.*, No. 12-cv-614, 2013 WL 5719500, at *7 (D.N.J. Oct. 21, 2013), *aff'd*, No. 13-cv-4777, 2015 WL 1046166 (3d Cir. Mar. 10, 2015). In *Delcath*, the facts were far more problematic than here: the defendant deliberately created the false impression that its device caused no more adverse effects than traditional therapies, when the truth was that *seven percent* of patients treated with its device *died*, while none in the control group died. The court relied in part on FDA's severe criticism of the device's "substantial and severe toxicity." 36 F. Supp. 3d at 335-36. Here, while the panel did vote unanimously against recommending approval, three of its members voted that EDAP had demonstrated safety, and several panel members praised EDAP for its rigor and honesty. *See supra* at 1.[19] *Delcath* is distinguishable.[20]

[19] Panel members also suggested that Ablatherm is as safe as competing therapies. *See* Ex. O at 195 ("If you're comparing it to patients who have radical prostatectomy, it has a similar safety protocol.") (Dr. Hanno); *id.* at 196 ("if I look at other choices, it's probably not that much different from either surgery or cryo surgery.") (Dr. Arduino).

[20] Additional factors further distinguish *Delcath* from this case. Whereas Delcath's use of a "new and relatively untested filter" supported an inference that "[d]efendants knew the results of their Phase III trials were not as strong as they represented," there is—contrary to plaintiff's say-so (Opp'n at 29)—no allegation that anything about EDAP's PMA submission was "new and relatively untested." The complaint in *Delcath* also featured testimony of four confidential witnesses, at least one of whom the Court credited in finding a strong inference of scienter; here, despite the plaintiff's effort to locate confidential witnesses, the Complaint here contains no

Otherwise, the attempt to create scienter by pointing to the FDA's end-of-class-period statements reduces to impermissible fraud by hindsight. "Defendants did not know, and had no reason to know, that the FDA would initially (and erroneously) reject its [application]." *Fort Worth Employers' Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 228 (S.D.N.Y. 2009) (rejecting allegations of scienter as improper fraud by hindsight). *See, e.g.*, *Kuyat v. BioMimetic Therapeutics, Inc.*, 747 F.3d 435, 442 (6th Cir. 2014) (affirming dismissal where FDA briefing document "was released at the end of the class period and well after the allegedly misleading statements were made," and thus "has little bearing on what the company did or did not know at the time the allegedly misleading statements were made").[21]

Finally, the suggestion that the competing inferences are, on balance, even (or that the scales tip in plaintiff's favor) is without merit. Just as in *BioMimetic*, plaintiff argues that defendants evinced an "unwillingness and inability to take the costly and time consuming steps necessary to properly demonstrate Ablatherm's efficacy and safety to the FDA." Opp'n at 30. But "[t]he notion that [the defendant] would recklessly forego necessary tests and studies or hide adverse events makes little sense . . . . Plaintiffs' own allegation is that [the drug candidate] is [the defendant's] flagship product and necessary to the company's success, begging the question why it would sabotage all of the company's efforts to that point." *BioMimetic*, 2013 WL 139521, at *17.[22] In any event, plaintiff omits that in response to the deficiency letter and the 100-day meeting, EDAP—far from refusing to take steps to try to assure the success of the PMA application—submitted a supplement using a new endpoint. *See supra* at 6.

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confidential witness testimony whatsoever.

[21] *Sanofi-Aventis* does not help plaintiff because the company hid the fact that the FDA had required additional studies. *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 564, 571 (S.D.N.Y. 2011).

[22] The court made a similar observation in rejecting the plaintiffs' theory of scienter in the *Keryx* case: "it is one thing to suggest that the scientists and analysts did their job poorly; it is another to suggest that the Company knew that they had done their job poorly, and nonetheless (either consciously or recklessly) made statements to hide those errors." *In re Keryx Biopharmaceuticals, Inc., Sec. Litig.*, No. 13-cv-1307-KBF, 2014 WL 585658, at *13 (S.D.N.Y. Feb. 14, 2014). Additionally, plaintiff's suggestion that the fact that Mr. Oczachowski "signed the misleading filings" bolsters an inference of scienter is hopelessly circular.

B. The Complaint Fails To Allege Motive

Having failed adequately to allege recklessness, plaintiff cannot establish scienter through his meager motive allegations. It is dispositive that the Complaint fails to allege any "concrete and personal benefit to the individual defendants resulting from the [alleged] fraud." Defs.' Mem. at 27 (citing *Kalnit*). In response, plaintiff invokes cases where scienter was established based on allegations that "*the very survival of the company*" was in jeopardy. Opp'n at 31. But those cases have no application here, where the Complaint contains no allegations that EDAP was even struggling, let alone on the brink of collapse.[23] Contrary to plaintiff's say-so, the "economic viability" of EDAP is in no way tied to the Company's ability to obtain FDA-approval of Ablatherm; EDAP has multiple business divisions, with operations in "Europe, the Americas, Asia and the rest of the world." Dulberg Decl. Ex. A at 18. Almost 80% of the Company's net sales are generated by its Urology Devices and Services ("UDS") division, and *not* from its HIFU division. *See id.* at 14 of 15.

As far as plaintiff's failure to allege a single instance of insider trading, in this Circuit, that pleading deficiency strongly undermines any inference of intent to commit fraud. *See Kalnit v. Eichler*, 99 F. Supp. 2d 327, 335 (S.D.N.Y. 2000) ("Fraudulent motive is generally demonstrated through allegations of insider trading or some other type of pecuniary gain by company insiders at the expense of shareholders."), *aff'd*, 264 F.3d 131, 142 (2d Cir. 2001) (affirming dismissal where "plaintiffs have not pointed to any specific benefit that would inure to the defendants that would not be either generalized to all corporate directors or beneficial to all shareholders, not just the defendant directors specifically").

[23] To be sure, EDAP said that "we depend on the success of our HIFU technology for future revenue growth and net income." Compl. ¶ 133. But nothing in that statement suggests that *FDA approval* of Ablatherm was critical, where the device already is approved and used to treat patients across Europe and many other countries.

III. Section 10(b) Does Not Apply To These Claims

In response to defendants' argument that Section 10(b) does not apply to plaintiff's claims under *Morrison v. National Australia Bank Ltd.*, plaintiff meekly offers only that "[b]ecause EDAP ADRs are securities that are listed and traded on NASDAQ, *Morrison* is satisfied." Opp'n at 35. But this argument is at odds with controlling Second Circuit law, which holds that the mere fact that a security is listed and traded on a domestic exchange is not enough to overcome the presumption against extraterritorial application of U.S. law. *Parkcentral Global Hub Ltd. v. Porsche Auto. Holdings SE*, 763 F.3d 198, 215, 218 (2d Cir. 2014) (per curiam) (*Morrison* "unmistakably made a domestic securities transaction (or transaction in a domestically listed security) *necessary* to a properly domestic invocation of § 10(b), such a transaction is *not alone sufficient* to state a properly domestic claim under the statute") (emphasis added).[24] Plaintiff offers nothing else to justify the extraterritorial application of U.S. law to the French defendants. As for plaintiff's invocation of several pre-*Porsche* cases that have applied Section 10(b) to claims involving purchases of ADRs on domestic exchanges, Opp'n at 33, another court in this District has correctly since concluded that those decisions "are entitled to little weight here, because it does not appear that the defendants in these actions argued that the Exchange Act does not extend to claims related to ADRs listed on a U.S. exchange." *United States v. Martoma*, No. 12-cr-973-PGG, 2013 WL 6632676, at *3 n.2 (S.D.N.Y. Dec. 17, 2013).[25]

CONCLUSION

For the foregoing reasons, the Complaint should be dismissed with prejudice.

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[24] Plaintiff's attempt to limit the holding in *Porsche* to the facts of that case, Opp'n at 34, ignores the broad language of the Second Circuit's holding.

[25] Plaintiff argues that the *Societe Generale* decision is distinguishable because the plaintiffs there purchased ADRs in a domestic *over-the-counter market* rather than on a domestic *exchange*. This distinction makes no difference; the *Societe Generale* court explicitly dismissed the complaint "*because trade in ADRs* is considered to be a predominantly foreign securities transaction," rendering Section 10(b) "inapplicable." *In re Societe Generale Sec. Litig.*, No. 08-cv-2495-RMB, 2010 WL 3910286, at *6 (S.D.N.Y. Sept. 29, 2010) (emphasis added).

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Respectfully submitted,

/s/ Michael G. Bongiorno
Michael G. Bongiorno
Peter A. Spaeth (admitted pro hac vice)
Andrew S. Dulberg (admitted pro hac vice)
Wilmer Cutler Pickering Hale and Dorr LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800 (t)
(212) 230-8888 (f)
michael.bongiorno@wilmerhale.com

Attorneys for EDAP TMS S.A. and Marc Oczachowski

CERTIFICATION

I hereby certify that on May 13, 2015, a copy of foregoing was filed electronically and served by mail on anyone unable to accept electronic filing. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system or by mail to anyone unable to accept electronic filing. Parties may access this filing through the Court's system.

/s/ Andrew S. Dulberg
Andrew S. Dulberg
WILMER CUTLER PICKERING HALE & DORR LLP
60 State Street
Boston, MA 02109
617 526-6000 (t)
617 526-5000 (f)
andrew.dulberg@wilmerhale.com